



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0622]

Best Practices in Developing Proprietary Names for Human Prescription Drug Products;

Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Best Practices in Developing Proprietary Names for Human Prescription Drug Products." This document provides guidance to sponsors on the development and selection of proposed proprietary names. This guidance describes best practices to help minimize medication errors and otherwise avoid adoption of proprietary names that contribute to violations of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations and provides a voluntary framework for evaluating proposed proprietary names before submitting them for FDA review. This guidance finalizes the draft guidance issued in May 2014 entitled "Best Practices in Developing Proprietary Names for the Drugs."

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including

attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-0622 for "Best Practices in Developing Proprietary Names for Human Prescription Drug Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a

written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lubna Merchant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4418, Silver Spring, MD 20993-0002, 301-796-5162, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Best Practices in Developing Proprietary Names for Human Prescription Drug Products." This guidance describes best practices to help minimize proprietary name-related medication errors and otherwise avoid adoption of proprietary names that contribute to violations of the FD&C Act and its implementing regulations. This guidance also describes the framework FDA uses in evaluating proprietary names that sponsors could use before submitting names for FDA review if they wish.

FDA has long recognized the importance of proprietary name confusion as a potential cause of medication errors and has addressed this issue repeatedly in recent decades. Our focus has been to develop and communicate to sponsors a systematic, standardized, and transparent approach to proprietary name evaluation within the product development, review, and approval process.

In the *Federal Register* of May 29, 2014 (79 FR 30852), FDA announced the availability of a draft guidance entitled "Best Practices in Developing Proprietary Names for Drugs." The guidance announced in this notice finalizes the draft guidance issued in May 2014. The Agency has carefully reviewed and considered the comments it received in developing this final version of the guidance.

FDA received several comments on the guidance and revised the guidance in response to these comments. The revisions include a) adding a note in the section discussing the United States Adopted Name (USAN) stating that FDA will no longer object to the use of two-letter

USAN stems in names for products that do not share any association with the stem in question; b) streamlining the name simulation study section based on the feedback received; c) providing clarifications to the section that discusses medical abbreviations, modifiers, and computational methods; d) separating the content pertaining to nonprescription proprietary names and issuing separate guidance to address the name development process for nonprescription drugs; e) revising the misbranding discussion for greater clarity and included information on one possible study methodology that sponsors may consider to test proposed names for misbranding concerns; and f) adding certain definitions and specific criteria for prescreening proprietary name candidates and updating definitions in the glossary and clarified terminology where needed. FDA also revised the document throughout to ensure consistency in terminology, clarified section headings, and reordered information for clarity where applicable.

Elsewhere in this issue of the *Federal Register*, FDA is announcing the availability of a draft guidance entitled "Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products." That draft guidance is issued in response to industry stakeholders' requests to specifically address the approaches for naming of human nonprescription drug products. The draft guidance is being issued to provide greater clarity on the considerations applicable to nonprescription drug products.

The guidance announced in this notice is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Best Practices in Developing Proprietary Names for Human Prescription Drug Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001, and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

III. Electronic Access

Persons with access to the internet may obtain the document at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, or <https://www.regulations.gov>.

Dated: December 4, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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